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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,141	HASTINGS ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-27* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election with traverse of Group I (claims 11-24), which are drawn to a food supplement, comprising lipoic acid or a derivative thereof, and creatine or a derivative thereof, classified in class 424 subclass 757 is acknowledged. The traversal is on the ground(s) that Groups I, II and III are largely coextensive because they are placed in the same classification. This is not found persuasive because the claims are drawn distinct and independent inventions because the product as claimed in Group I can be used in a materially different process of using that product as indicated in the previous restriction requirement and that claimed method in Group II and Group III are unrelated because they involved different effects and different operations as Group II is related to supplementing the diet while Group III is related to enhancing muscle size or strength. Therefore, a serious burden would be place on the Examiner, particularly, required non-patent literature search to search all of the unrelated inventions. Therefore, the restriction requirement made in the previous Office Action is deemed proper and made FINAL.

Accordingly, claims 11-24 have been examined and claims 25-27 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13, 14 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 11, 13 and 14, the term "derivatives" in claims 11 is indefinite since it is not clear which derivatives Applicants' are referring to since there is a lack of such derivatives set forth in the specification. One of ordinary skill in the art could not ascertain and interpret the metes and bounds of the term "derivatives" of creatine because that "derivatives" of the compound in the claims could read on any modification of the compound having widely varying groups. It is noted that the specification does not describe any chemical structures of substituents to be employed as a derivatives of creatine. Accordingly, one of ordinary skill in the art would not be able to practice the employment of the "derivatives" instantly claimed.

With regard to claim 20 the phrase "soy protein is water extracted" is unclear whether the isolate is solid extracted with water or whether it is water contained liquid.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Gardiner (U.S.Patent No. 6,136,339).

Gardiner teaches food supplement compositions comprising lipoic acid or a derivative thereof and creatine or a derivative thereof. (abstract, claims particularly, claims 1 and 14). Gardiner exemplifies food supplements comprising lipoic acid and creatine monohydrate. (column 5, Examples 1 and 2). Gardiner teaches glutamine can be included in the supplements. (see claims 35 and 36, particularly claim 36). Therefore, above teachings clearly anticipate Applicants' the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner (U.S.Patent No. 6,136,339)(Gardiner'339) in view of Hastings et al. (U.S.Patent No. 6,224,871B1), Ribnicky et al. (U.S.Patent No. 6,893,627 B2), Brantman (U.S.Patent No. 4,687,782), Michnowski (U.S.Patent No. 4,832,971), Gardiner

(U.S.Patent No. 5,817,329) (Gardiner '329), Riley (U.S.Patent No. 5,976,568) and Ecker (U.S.Patent No. 3,894,148).

Gardiner (Gardiner'339) teaches food supplement compositions comprising **lipoic acid** or a derivative thereof, **creatine, alanine, l-carnitine** useful for supplementing the diet of an athlete and particularly for enhancing an athlete's muscle size or strength. (abstract, claims particularly, claims 1, 14 and 35). Gardiner (Gardiner'339) exemplifies food supplements comprising **lipoic acid** and **creatine monohydrate**. (column 5, Examples 1 and 2). Gardiner (Gardiner'339) teaches **glutamine** can be included in the supplements. (see claims 35 and 36, particularly claim 36).

Gardiner (Gardiner'339) does not teach the fructose, soy protein isolate, l-carnitine, grape seed extract, coenzyme Q10, *piper nigrum* extract, alpha lipoic acid, l-leucine, l-alanine and glycine, l-arginine, l-lysine, conjugated linoleic acid, phosphatidylserine/phosphatidylcholine complex, ornithine alpha-ketoglutarate, medium chain triglycerides, lecithin and their specific amounts, and the daily serving amounts.

Ecker teaches the process for **enhancing the energy** metabolism and physical **endurance of athletes** comprising administering **fructose**. Ecker teaches that fructose is an energy food and can be utilized by the cells of the body to derive energy. Ecker teaches that various advantages of utilization of fructose versus glucose. (abstract, column 3, lines 21-67, formulations on column 5 and 6).

Michnowski teaches a nutritional **athletic bar** comprising **soy proteins, such as isolates** or concentrates and **fructose granules**. (title, abstract, column 5, lines 49-67,

column 6, lines 10-20). Michnowski teaches that such nutritional bars are suitable as snacks for hikers, skiers, mountain climbers and athletes. (column 7, lines 65-68).

Ribnicky et al. teach a variety of substances for improving nutrition, particularly, sports nutrition comprising **alpha-lipoic acid**, **phosphatidylserine**, **phosphatidylcholine**, **conjugated linoleic acid**, **L-carnitine** and **conventional amino acid**. (column 10, line 59 - column 11, line 35).

Hastings et al. teach a dietary supplement for nutritional promoting composition comprising ***piper nigrum* extract**, **flavoring agent**, and **lecithin**. (abstract, Example 2).

Gardiner (Gardiner '329) teaches a composition useful as a diet supplements for athletes and body builders comprising carnitine, **ornithine alpha-ketoglutarate**, **l-glutamine**, **l-leucine**, **l-isoleucine**, **l-glycine** and **l-valine**. (abstract, column 4, line 24, claims 6-12). Gardiner teaches that **ornithine alpha-ketoglutarate** prevents muscle breakdown. (column 5, lines 13-15).

Brantman teaches a combinations of **amino acids (carnitine, glutamine, isoleucine, leucine and valine) and soy protein**, **medium-chain triglycerides** for supplementing the diet of an athlete. (abstract, Example I, claim 1).

Riley teaches multivitamin and mineral supplementation comprising Coenzyme Q-10, alpha lipoic acid, and **grape seed extract**. (abstract, column 20-21, table).

It would have been obvious to one of ordinary skill in the art to modify Gardiner's (Gardiner'339) nutritional food supplement and incorporate other agents such as fructose, soy protein isolate, l-carnitine, grape seed extract, coenzyme Q10, piper

nigrum extract, alpha lipoic acid, l-leucine, l-alanine and glycine, l-arginine, l-lysine, conjugated linoleic acid, phosphatidylserine/phosphatidylcholine complex, ornithine alpha-ketoglutarate, medium chain triglycerides and lecithin because all these agents are useful and effective for providing diet supplement and suitable for nutritional diet as taught by individual references. Therefore, it would be expected that the combination of components would be beneficial in supplementing nutrition, particularly for athletes who needs various nutritional supplement for enhancing energy as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). The amounts of active agents to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
October 26, 2007